WRIGHT
MEDICAL TECHNOLOGY, INC.
5677 AIRLINE ROAD
ARLINGTON, TN 38002
901-867-9971

K961572

SEP 17 1996

Contact Person: Judy English
Date Prepared: September 8, 1996

510(k) Summary

Trade Name:	VERSALOK™ Screw Assembly, Product line addition to WRIGHTLOCK™ Posterior Spinal Fixation System
Common Name:	Spondylolisthesis Spinal Fixation Device System
Predicate Devices:	WRIGHTLOCK™ Posterior Spinal Fixation System (Wright Medical Technology, Inc.) MOSS® Miami System (DePuy)

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR §807.92.

Description/Intended Use The VERSALOK™ Screw Assembly is a polyaxial screw assembly consisting of screws, locking sleeves, and caps. The system is designed to accommodate the rods of the commercially available WRIGHTLOCK™ Posterior Spinal Fixation System (K950074--SE 08/11/95). The system features a low profile as well as a top loading design. It allows for up to 6mm offset from the rod and up to 30 degrees of angulation in all planes prior to final locking. The VERSALOK™ Screw Assembly is available in a range of sizes to fit varying anatomical requirements.

The VERSALOK™ Screw Assembly is supplied as an alternative component for use with the WRIGHTLOCK™ Posterior Spinal Fixation System to fix the spine for appropriate indications. Limited indications apply when used as a pedicle screw.

A WRIGHTLOCK™ construct with screws attached to the pedicles of the lumbar and sacral spine (L3 to S1) and autogenous bone graft may be used for the treatment of severe spondylolisthesis (Grade 3 and Grade 4) at the fifth lumbar - first sacral (L5-S1) vertebral joint. The device is intended to be implanted using a posterior surgical approach and removed after development of a solid fusion mass.

When not used as a pedicle screw fixation system, various combinations of the system are also indicated to provide temporary stability of the thoracic, thoracolumbar, or lumbar spine (T1 to S1) during bony fusion healing secondary to: (1) Unstable spinal fractures (such as fracture dislocations) or spinal tumors; (2) Degenerative disk diseases of the spine (defined as back pain of diskogenic origin with degeneration of the disk confirmed by radiographic studies); (3) Spinal curvatures (such as idiopathic scoliosis, neuromuscular scoliosis/kyphoscoliosis with associated paralysis or spasticity, and secondary to spinal fractures) which are: progressive, despite other forms of treatment; detrimental to cardiopulmonary function; interfering with spinal mechanics or causing severe back pain; or cosmetically unacceptable, progressive, and painful.

Material Components in the VERSALOK™ Screw Assembly are manufactured from stainless steel conforming to ASTM F 1314.

Summary of Technological Differences The VERSALOK™ Screw Assembly is a product line addition to the WRIGHTLOCK™ Posterior Spinal Fixation System and there are few differences between the devices. Both devices have the same intended use and are manufactured from the same material. They are different in that the VERSALOK™ Screw Assembly is a polyaxial screw option to the system that previously included only a monoaxial screw. In addition, the design of the VERSALOK™ Screw Assembly differs from the screw assembly of the MOSS® Miami System in minor design features and locking mechanism; however, the differences only address surgeon preferences and do not impact the function or negatively impact the safety of the device.

Testing Summary The VERSALOK™ Screw Assembly tested with the following mean results: fatigue endurance limit of 353N, axial push strength of 1096N, and torsional grip strength of 1.95Nm. Based on these results, the VERSALOK™ Screw Assembly should perform adequately when subjected to normal physiological loading.